Remarks

This Amendment is in response to the Office Action dated **June 1, 2007.**

Rejections

35 U.S.C. §102(b)

Claims 1-3, 6-11, 14, 16, 17 and 20-24

Claims 1-3, 6-11, 14, 16, 17 and 20-24 have been rejected under 35 U.S.C. §102(e) as being anticipated by US 5,201,706 to Noguchi et al. It is asserted in the Office Action that:

> Noguchi teaches a dilation balloon catheter comprising fibers 12 in a matrix material 10, said fibers embedded in the matrix material of the balloon. The fibers are viewed as being "embedded" because one of the common definitions for "embedded" is: --to surround closely-- (www.m-w.com). As seen in Fig. 3, the fiber layer 12 is surrounded closely by the elastic layer 10....

Office Action, page 3, lines 1-5.

Applicants disagree.

Claim 1 of the present application is directed to a dilatation balloon including fibers and a matrix material, the fibers are embedded in the matrix material of the balloon, a feature not disclosed by Noguchi et al. However, claim 1 has also been amended to incorporate the limitations of canceled claim 7 wherein the fibers are non-elastomeric. This amendment is for the purpose of expediting prosecution. No new matter has been added.

Independent claim 14 is directed to a catheter system having an inflatable portion including a matrix material and fibers embedded in the matrix material. Claim 14 has also been amended to incorporate the limitations of claim 15 wherein the catheter system includes an

intravascular stent disposed on the inflatable portion. Support is also found at least from the Summary of the Invention, page 4, lines 25-28 and page 8, lines 16-22. No new matter has been added.

Applicants still maintain, however, that Noguchi et al. fail to disclose fibers embedded in a matrix material. Noguchi et al. also fail to disclose using non-elastomeric fibers as recited in amended claim 1, and fail to disclose the balloon described therein for use in intravascular stent delivery as recited in amended claim 14.

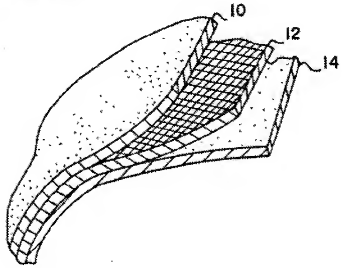
Applicants submit that in the embodiments recited in claims 1 and 14, the fibers are completely surrounded by the matrix material. The fibers are in the material of the balloon wall. For example, see page 11, lines 27-32 of the present specification and col. 2, lines 112-120 of 1,566,674.

Applicants submit that the balloon structure shown in Fig. 3 of Noguchi, on the other hand, "...consists of a three-layered structure of an outer elastic film 10, a cylindrical body 12 of a composite yarn and an inner elastic film 14." Col. 3, lines 10-12 of Noguchi et al. Noguchi et al. form the three layered balloon structure by forming each film and the composite yard separately and then assembling the parts. "A cylindrically knitted fabric was separately prepared by knitting the composite yarn by means of a knitting machine wherein 50 knitting needles were arranged on a circumference with a diameter of 20 mm." See Example 1, cols 5, lines 67-68 to col. 6, lines 1-11, and particularly col. 6, lines 4-8. There is nothing in Noguchi et al. to suggest that the three-layered balloon structure is formed in any other way.

Therefore, the cylindrical body 12 of composite yard is layered or sandwiched between the outer elastic film 10 and the inner elastic film 14 but the fibers are not embedded therein and the three layers of the Noguchi et al. balloon structure are separate entities. This is

clearly seen by Fig. 3 of Noguchi et al., reproduced below for convenience.

Fig. 3



In fact, as can be clearly seen from this figure, while the cylindrical body 12 is sandwiched between films 10 and 14, clearly, the fibers are not embedded in film 10 or 14. In fact, even by the loose definition of "embedded" employed in the Office Action, the fibers of the cylindrical body 12 of the Noguchi et al. structure are not even "surrounded closely by" either of the elastic films 10 or 14. For example, using www.m-w.com, referred to in the Office Action, surround is defined as "to enclose all sides: envelop". Applicants submit that all sides of the fiber are not enclosed by film 10 or 14 of the Noguchi et al. three-layered balloon structure.

Anticipation requires, under 35 U.S.C. §102, that all of the elements of the claimed invention be disclosed in a single prior art reference as arranged in the claim. "Anticipation" means that the claimed invention was previously known, and that all of the elements and limitations of the claim are described in a single prior art reference." *Hakim v. Cannon Avent*

Group PLC, 81 USPQ2d 1900, 1905 (Fed. Cir. 2007) (referring to *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 [1 USPQ2d 1241] (Fed. Cir. 1986) ("Under 35 U.S.C. §102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference.")). See also MPEP 2131 (referring to *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q.2d (BNA) 1429, 1431 (Fed. Cir. 1997); and *Glaxo Inc. v. Novopharm Ltd.,* 52 F.3d 1043, 1047, 34 U.S.P.Q.2d (BNA) 1565, 1567 (Fed. Cir. 1995).

Applicants submit that not even by the definition of embedded which is employed in the Office Action, can the balloon structure of Noguchi et al. anticipate either claims 1 or 14. The cylindrical body 12 of composite yarn disclosed by Noguchi et al. is simply not embedded within the elastic films 10 or 14.

Furthermore, as mentioned above, Noguchi et al. disclose a specific composite yarn, and fail to disclose using non-elastomeric fibers only. Therefore, claim 1 cannot be anticipated for this reason as well because all of the elements are not disclosed by Noguchi et al. as arranged in the claim.

Claims 2-3 and 6-11 depend from claim 1 and are not anticipated by Noguchi et al. for at least the reasons that claim 1 is not anticipated by Noguchi et al.

As also mentioned above, Noguchi et al. fail to disclose the balloons described therein for the purpose of delivering an intravascular stent. Claim 14 can therefore not be anticipated by Noguchi et al. for this additional reason because all of the elements of claim 14 are not disclosed by Noguchi et al.

Claims 16, 17 and 20-24 depend from claim 14 and are not anticipated by Noguchi et al. for at least the reasons that claim 14 is not anticipated by Noguchi et al.

Applicants respectfully request withdrawal of the rejection of claims 1-3, 6-11, 14, 16, 17 and 20-24 under 35 U.S.C. §102(e) as being anticipated by US 5,201,706 to Noguchi et al.

35 U.S.C. §103(a)

Claims 5 and 19

Claims 5 and 19 have been under 35 U.S.C. §103(a) as being unpatentable over Noguchi et al. and in view of UK 1,566,674 to Hanecka et al. The Office Action asserts that:

> Noguchi teaches a fabric fiber body but is silent with regards to the orientation of the fabric body having a helical pattern. However, Hanecka teaches a similar reinforced balloon catheter having a fabric body formed with a helical pattern (page 2, line 117). Therefore, *it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fabric fiber body of Noguchi to include a helical pattern because it would allow the inflatable balloon to expand to a predetermined size that is determined or controlled by said helical pattern.*

Office Action, page 4, section 6 (emphasis added).

As discussed above, claim 1 has been amended to recite that the fibers are non-elastomeric.

Applicants submit that Noguchi et al. discloses a catheter with a balloon that is reinforced with a very specific type of composite yarn:

> A catheter with a balloon characterized by a balloon reinforced with a composite yarn consisting of *an elastic yarn and a non-elastic yarn with a larger free length of the non-elastic yarn than that of said elastic yarn*....

Abstract of Noguchi et al. (emphasis added).

Noguchi et al. describe a range of specific length ratios of the elastic yarn to the non-elastic yarn:

> In the catheter with a balloon of the present invention, the ratio of the free length of an elastic yarn to a non-elastic yarn is preferably 0.15-0.5 and more preferably 0.2-0.35. *If this ratio is larger, the balloon is not sufficiently expandable, and if too small, the reinforcing effect of the non-elastic yarn is reduced and breakage of the balloon, when expanded, easily occurs.*

Noguchi et al., col. 2, lines 43-50.

Therefore, Noguchi et al. disclose only this composite yarn for use therein, and fail to disclose the use of Applicants' non-elastomeric fibers as recited in claim 1 which are not a composite yarn.

Hanecka discloses a bulb catheter that can be reinforced by means of a synthetic fabric that is helically oriented. Hanecka, filed February 17, 1977, is silent as to what the synthetic fabric is.

Therefore, this combination lacks the element of the fibers being specifically non-elastomeric and claim 5 as amended, is not obvious over Noguchi et al. in view of Hanecka.

Claim 19, as amended, now recites that the catheter assembly includes a stent disposed on the inflatable portion.

Neither Noguchi et al. nor Hanecka disclose a stent.

Therefore, the combination lacks a notable element of claim 19, and claim 19, as amended, is not obvious over this combination.

Applicants respectfully request withdrawal of the rejection of claims 5 and 19 under 35 U.S.C. §103(a) as being unpatentable over Noguchi et al. and in view of UK 1,566,674 to Hanecka et al.

Claims 12 and 25

Claims 12 and 25 are rejected under 35 USC §103(a) as being unpatentable over

Noguchi et al. It is asserted in the Office Action that:

> Noguchi is silent with regards to a non-elastic layer 10, 12 and an elastic body 12. However, Noguchi teaches the recited polymers in the claims, which are capable of having the same characteristics recited in the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the layers 10, 12 to be non-elastic and the fiber body to be elastic since Noguchi teaches identical materials that are capable of having the same characteristics. It would also be a mere design choice to make the layers 10, 12 be non-elastic and the fiber body be elastic since the Applicant has not disclosed that having non-elastic layers 10, 12 or an elastic body 12 solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with the reversal of parts taught by Noguchi.

Office Action, pages 4-5, section 7.

Applicants disagree.

As discussed above, Noguchi et al. disclose a very specific composite yarn for use therein including an elastic yarn and a non-elastic yarn with a larger free length of the non-elastic yarn than that of said elastic yarn. See Abstract.

Not only that, however, Noguchi et al. disclose that a very specific ratio of the non-elastic yarn to the elastic yarn wherein the ratio of the free length of elastic to non-elastic 0.15-0.5 to 0.2-0.35, therefore, at least about 1/3 or a very significant portion of the free length is elastic yarn. Furthermore, Noguchi et al. disclose that if this ratio is too large, the balloon does not have sufficient expansibility, or if the ratio is too small, the balloon breaks upon expansion. See col. 2, lines 43-50.

Applicants have amended claim 1 to recite that the fibers are *non-elastomeric*.

It would not be an obvious modification based on the disclosure of Noguchi et al., to employ only non-elastomeric fibers because without using the composite yarn of Noguchi et al., and employing only non-elastomeric fibers, one would not have sufficient expansibility, and would expect balloon breakage during expansion. Therefore, there would not be a reasonable

expectation of success in modifying the teaching of Noguchi et al. in this fashion.

The prior art can be modified or combined to reject claims as *prima facie* obvious providing that there is a reasonable expectation of success. See MPEP 2143.02 citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim 1, as amended, is therefore not obvious over Noguchi et al. and claim 12 which depends from claim 1 is not obvious over Noguchi et al. for at least the reasons that claim 1 is not obvious over Noguchi et al.

Claim 25 depends from claim 14 and recites that the inflatable portion is formed from a non-elastomeric material enclosed within an elastomeric material. Claim 25 is not obvious over Noguchi et al. for at least the reasons that claim 1 is not obvious over Noguchi et al. because Noguchi et al. fails to disclose using only a non-elastomeric material, and modifying the balloon disclosed by Noguchi et al. in this manner is not a predictable modification because Noguchi et al. teach that a specific composite yarn must be employed or the balloon will not have sufficient expansibility, or it would break. Therefore, there is no benefit to modifying the balloon of Noguchi et al. in the manner recited in independent claim 14.

If one of skill in the art cannot implement a predictable variation, or see the benefit of doing so, the combination does not preclude patentability under 35 U.S.C. §103(a). See *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007).

Claim 14 has also been amended to recite that a stent is disposed on the inflatable portion. It is also not obvious from the Noguchi et al. disclosure to employ the balloons described therein for stent delivery. Claim 25 depends from claim 14 is not obvious over Noguchi et al. as discussed above, and also for at least the reasons that claim 14 is not obvious over Noguchi et al.

Applicants respectfully request withdrawal of the rejection of claims 12 and 25 under 35 U.S.C. §103(a) as being obvious over Noguchi et al.

Claims 13, 15, 26 and 27

Claims 13, 15, 26 and 27 are rejected under 35 USC. 103(a) as being unpatentable over Noguchi et al. in view of US 5,100,429 to Sinofsky et al. It is asserted in the Office Action that:

> Noguchi teaches an inflatable balloon catheter that is capable of expanding a stent but is silent with regards to the combination of the catheter and the stent. However, Sinofsky teaches a stent 112 releasably attached or mounted by a bond (coL 9, lines 51-53) to an inflatable portion of a catheter 120, wherein the stent is capable of retaining a deployed configuration. Therefore, it would have been obvious to one of ordinary skill in the art to use a stent with the inflatable balloon of Noguchi because the reinforced inflatable balloon of Noguchi would allow the use of high-pressure within the balloon to fully inflate the balloon without rupturing said balloon.

Claim 1, as amended, has been discussed above and is neither anticipated by, nor obvious over Noguchi et al. because the disclosure of Noguchi et al. does not provide a reasonable expectation of success when modifying the balloon as recited in Applicants' independent claim 1. Claim 13 depends from claim 1 and is not obvious over Noguchi et al. for at least the reasons that claim 1 is not obvious over Noguchi et al.

Claims 15, 26 and 27 depend from claim 14.

Claim 14 has been amended to recite that the catheter system includes an intravascular stent, i.e. used in blood vessels, disposed on the inflatable portion.

Applicants submit that Noguchi et al. is directed to a balloon for treatment of a heart valve.

Sinofsky is directed to an endovascular apparatus for treating blood vessels. See

at least Abstract of the Invention and Background of the Invention.

Noguchi et al., on the other hand, is directed to balloons for use in treating heart valves. See at least column 1, lines 61-67. While the balloon is delivered through a blood vessel in a reduced state, in its expanded state, it has a much larger diameter than an intravascular stent, as well as a much larger expanded diameter than the corresponding balloon used for the delivery of an intravascular. For example, see col. 6, liens 32-48, wherein the balloon was expanded to a cylindrical shape with a diameter of about 28 mm. See also col. 7, lines 17-27 wherein the balloon was exhibited a maximum diameter of about 30 mm, and minimum shrink diameter of 4-5 mm.

While Sinofsky et al. is silent as to absolute values for the reduced and expanded diameter of the endovascular apparatus disclosed therein, intravascular stents for implanting in a blood vessel, and the corresponding stent delivery balloons, have significantly smaller diameters than those balloons disclosed by Noguchi et al. See commonly assigned U.S. Patent No. 7081130 to Jang et al.:

> When fully expanded Stent 10 of FIGS. 4A and 4B has an internal diameter of up to 5.0 mm, while maintaining an acceptable radial strength and fatigue tolerance. The crimped stent outer diameter can be as small as 1.0 mm or less depending on the condition of the underlying delivery balloon profile; A small crimped outer diameter is especially important if stent delivery is to be attempted without predilation of the target site. When the stent is optimally crimped over the delivery balloon, the surface of the crimped stent is smooth allowing for no snagging of the stent struts during either forward or backward movement through a vessel.

Jang, US 7081130, col. 8, lines 54-65.

> Typical coronary vascular stents have expanded diameters that range from 2.5 to 5.0 mm. However, a stent with high radial strength and fatigue tolerance that expands to a 5.0 mm diameter may have unacceptably high stent metal fraction when used in smaller diameter vessels. If the stent metal fraction is high, the chances of acute thrombosis and restenosis potential will increase. Even with the

> same metal fraction a smaller caliber vessel is more likely than a larger one to have a high rate of thrombosis. It is, therefore, preferred to have at least two different categories of stents for coronary application, for example, small vessels stents for use in vessels with diameters from 2.5 mm, to 3.0 mm, and large vessel stents for use in vessels with diameters from 3.0 mm. to 5.0 mm. Thus, both small vessels and large vessels when treated with the appropriate sized stent will contain stents of similar idealized metal fraction.

Jang, US 7081130, col. 11, lines 58-67 to col. 12, lines 1-6.

One would not employ a balloon such as that disclosed by Noguchi et al. for delivery of an intravascular stent or the endovascular apparatus such as that disclosed by Sinofsky. They are much too large, and obviously have expansion properties that are significantly different than the balloons used for intravascular stent delivery because they are expanded by a significantly larger factor. As discussed above, balloons disclosed by Noguchi et al. have an expanded diameter of 30 mm, and a reduced diameter of 4-5 mm, while intravascular stents have an expanded diameter of 2.5-5 mm and a reduced diameter of 1 mm. See Jang for example.

Therefore, one would simply not use a balloon as disclosed by Noguchi et al. for intravascular stent delivery or for an endovascular apparatus as disclosed by Sinofsky et al. Therefore, claim 14 as amended is not obvious over Noguchi et al. in view of Sinofsky et al.

Applicants respectfully request withdrawal of the rejection of claims 15, 26 and 27, depending from claim 14, as these claims are not obvious over Noguchi et al. in view of Sinofsky et al. for at least the reasons that claim 14 is not obvious over Noguchi et al. in view of Sinofsky et al.

CONCLUSION

Claims 1-3, 5, 6, 8-14, 16, 17 and 19-27 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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